

## § 139.117

## 21 CFR Ch. I (4–1–00 Edition)

(3) Each such food may also contain as an optional ingredient added calcium in such quantity that each pound of the finished food contains not less than 500 mg. and not more than 625 mg. of calcium (Ca);

(4) Each such food may also contain as an optional ingredient partly defatted wheat germ but the amount thereof does not exceed 5 percent of the weight of the finished food;

(5) Each such food may be supplied, wholly or in part, with the prescribed quantity of any substance referred to in paragraphs (a) (1), (2), and (3) of this section through the use of dried yeast, dried torula yeast, partly defatted wheat germ, enriched farina, or enriched flour, or through the direct additions of any of the substances prescribed in paragraphs (a) (1), (2), and (3) of this section.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) (1) and (2) of this section may be added in a harmless carrier which does not impair the enriched macaroni product, such carrier being used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished enriched macaroni product.

(b) Enriched macaroni is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 139.110(b).

(c) Enriched spaghetti is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 139.110(c).

(d) Enriched vermicelli is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Enriched Macaroni product"; or alternatively, the name is "Enriched macaroni", "Enriched spaghetti", or "Enriched vermicelli", as the case may be, when the units of the food comply with the

requirements of paragraphs (b), (c), or (d) respectively of this section.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993; 61 FR 8797, Mar. 5, 1996]

### § 139.117 Enriched macaroni products with fortified protein.

(a)(1) Each of the foods for which a standard of identity is prescribed by this section is produced by drying formed units of dough made with one or more of the milled wheat ingredients designated in §§ 139.110(a) and 139.138(a), and other ingredients to enable the finished food to meet the protein requirements set out in paragraph (a)(2)(i) of this section. Edible protein sources, including food grade flours or meals made from nonwheat cereals or from oilseeds, may be used. Vitamin and mineral enrichment nutrients are added to bring the food into conformity with the requirements of paragraph (b) of this section. Safe and suitable ingredients, as provided for in paragraph (c) of this section, may be added. The proportion of the milled wheat ingredient is larger than the proportion of any other ingredient used.

(2) Each such finished food, when tested by the methods described in the cited sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference (copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC), meets the following specifications:

(i) The protein content ( $N \times 6.25$ ) is not less than 20 percent by weight (on a 13 percent moisture basis) as determined by the method in section 14.142. The protein quality is not less than 95 percent that of casein as determined on the cooked food by the method in sections 43.212 through 43.216 of the official methods.

(ii) The total solids content is not less than 87 percent by weight as determined by the method in section 14.133 of the official methods.

(b)(1) Each food covered by this section contains in each pound 5 milligrams of thiamin, 2.2 milligrams of riboflavin, 34 milligrams of niacin or niacinamide, and 16.5 milligrams of iron.

(2) Each pound of such food may also contain 625 milligrams of calcium.

(3) Iron and calcium may be added only in forms which are harmless and assimilable. The enrichment nutrients may be added in a harmless carrier used only in a quantity necessary to effect a uniform distribution of the nutrients in the finished food. The requirements of paragraphs (b) (1) and (2) of this section shall be deemed to have been met if reasonable overages, within the limits of good manufacturing practice, are present to assure that the prescribed levels of the vitamins and mineral(s) are maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) The safe and suitable ingredients referred to in paragraph (a) of this section are ingredients that serve a useful purpose, e.g., to fortify the protein or facilitate production of the food, but they do not include color additives, artificial flavorings, artificial sweeteners, chemical preservatives, or starches. Ingredients deemed suitable for use by this paragraph are added in amounts that are not in excess of those reasonably required to achieve their intended purposes. Ingredients are deemed to be safe if they are not food additives within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act, or in case they are food additives, if they are used in conformity with regulations established pursuant to section 409 of the act.

(d)(1) The name of any food covered by this section is "Enriched Wheat \_\_\_\_\_ Macaroni Product—with Fortified Protein", the blank being filled in with appropriate word(s) such as "Soy" to show the source of any flours or meals used that were made from nonwheat cereals or from oilseeds. In lieu of the words "Macaroni Product" the word "Macaroni", "Spaghetti", or "Vermicelli", as appropriate, may be used if the units conform in shape and size to the requirements of § 139.110 (b), (c), or (d).

(2) When any ingredient, not designated in the part of the name pre-

scribed in paragraph (d)(1) of this section, is added in such proportion as to contribute 10 percent or more of the quantity of protein contained in the finished food, the name shall include the statement "Made with \_\_\_\_\_", the blank being filled in with the name of each such ingredient, e.g., "Made with nonfat milk".

(3) When, in conformity with paragraph (d) (1) or (2) of this section, two or more ingredients are listed in the name, their designations shall be arranged in descending order of predominance by weight.

(4) In the case of a food made to comply with another section of this part, but which also meets the compositional requirements of this section, it may alternatively bear the name set out in that other section.

(e) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14409, Mar. 15, 1977, as amended at 47 FR 11829, Mar. 19, 1982; 49 FR 10099, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2878, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

EFFECTIVE DATE NOTE: Section 139.117 was stayed in its entirety at 43 FR 11695, Mar. 21, 1978.

#### § 139.120 Milk macaroni products.

(a) Milk macaroni products are the class of food, each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

(1) Milk is used as the sole moistening ingredient in preparing the dough; or in lieu of milk one or more of the milk ingredients specified in paragraph (f) of this section is used, with or without water, in such quantity that the weight of milk solids therein is not less than 3.8 percent of the weight of the finished milk macaroni product; and

(2) None of the optional ingredients permitted by § 139.110(a) (1) and (2) is used. When the optional ingredient gum gluten (§ 139.110(a)(5)) is added, the